UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/643,866 | 08/20/2003 | Leigh T. Canham | 2490-30 | 5193 |

23117 7590 09/30/2008
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

| EXAMINER | |
|---|---|
| ALSTRUM ACEVEDO, JAMES HENRY | |
| ART UNIT | PAPER NUMBER |
| 1616 | |
| MAIL DATE | DELIVERY MODE |
| 09/30/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/643,866 | CANHAM, LEIGH T. | |
| | Examiner | Art Unit | |
| | JAMES H. ALSTRUM ACEVEDO | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *46-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/000,258 and 09/964,361.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**Claims 46-48 are pending.** Claim 86 was previously cancelled. Claims 49-85 are newly cancelled. Receipt and consideration of Applicants' remarks/arguments and amended claim set submitted on June 17, 2008 are acknowledged.

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/17/08 has been entered.

### *Election/Restrictions*

Applicant's election of Group I (claims 46-69, 71-73, 81, and 86) in the reply filed on November 27, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, **the election has been treated as an election without traverse** (MPEP § 818.03(a)).

**The requirement is still deemed proper and is therefore made FINAL.**

### *Priority*

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copies of GB 9524242.6 and GB 9611437.6 have been filed in

parent Application Nos. 09/000,258 (now U.S. Patent No. 6,322,895), 09/964,361 (now U.S. Patent No. 6,666,214), and PCT/GB96/01863), filed on 01/30/1998, 09/28/2001, and 08/01/1996, respectively.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on August 3, 1995. It is noted, however, that applicant has not filed a certified copy of the GB 9515956.3 application as required by 35 U.S.C. 119(b). The Examiner has reviewed the parent applications and priority document, **GB 9515956.3, filed August 3, 1995 in the United Kingdom was not in any of the parent files**.

Receipt is acknowledged of a certified copy of the GB 951596.2 application. However, GB 951596.2 is **NOT referred to in the oath or declaration or in an application data sheet**. If this copy is being filed to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. 119(b). If the application being examined is an original application filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. See 37 CFR 1.55(a)(1)(i). If the application being examined has entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and Regulations of the PCT. See 37 CFR 1.55(a)(1)(ii). Any claim for priority under 35 U.S.C. 119(a)-(d) or (f) or 365(a) or (b) not presented within the time period set forth in 37 CFR 1.55(a)(1) is considered to have been

waived. If a claim for foreign priority is presented after the time period set forth in 37 CFR 1.55(a)(1), the claim may be accepted if the claim properly identifies the prior foreign application and is accompanied by a grantable petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55(c).

### *Terminal Disclaimer(s)*

The terminal disclaimer filed on 1/14/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,666,214 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 46-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is maintained** for the reasons of record set forth in the office action mailed on March 6, 2007 and restated below with amendments to reflect the currently pending claims.

Applicant claims a method of growing natural host tissue in an implant comprising the step of placing a sample of resorbable porous silicon in a living animal or human and allowing the implanted resorbable porous silicon to degrade while in the living animal or human and be

replaced with natural animal or human tissue. Applicant indicates that support for the currently amended and pending claims is found in original claims 29 and 31 (shown below).

**29. The use of bioactive silicon for the construction of a device (300, 500) for use in a living human or animal body characterized in that the silicon is at least partly crystalline.**

**31. Bioactive silicon (20, 520) incorporated in a device (300, 500) suitable for use in a living human or animal body characterized in that the silicon is at least partly crystalline.**

The instant specification does not describe any method of growing natural host tissue in an implant as described above. It is noted that the specification states that bioactive materials may be considered to be any material that is suitable for implantation ([0003]). The doping of calcium into silicon via "ion implantation" is briefly described in [0070]; however, this is unrelated to the placement of resorbable silicon into a living human or animal. In paragraph [0088] of the specification, it is written, "The process of enhanced mineral deposition may be beneficial in the coating of silicon based integrated circuits prior to their implantation in the body;" however this does not constitute an adequate description of growing natural host tissue in an implant as described above to demonstrate possession of the claimed of growing natural host tissue in an implant as described above. In paragraph [0096] Applicants' suggest that "surgical implants" could be coated with polysilicon in order to increase adhesion to bone. This statement fails to provide adequate description and guidance of the claimed of growing natural host tissue in an implant as described above to demonstrate possession of the claimed method of

implantation. Furthermore, it is noted that original claims 29 and 31 recite that the silicon is partly crystalline. Applicants' currently amended claims do not require that the resorbable silicon is partly crystalline. It is also noted that a "use claim" with no specific step recited therein cannot be the basis of written support for a claimed method reciting specific steps, because the phrase "for use in a living human or animal body..." is vague concerning what steps if any are implied, required, and/or intended by such phraseology.

***Response to Arguments***

Applicant's arguments filed June 17, 2008 have been fully considered but they are not persuasive. Applicants' traversal is based on their belief that the claim amendments have overcome the instant rejection. The Examiner respectfully disagrees. Amendment of the preamble of the rejection claims to recite, "A method of growing natural host tissue in an implant..." as described above does not cure the lack of adequate written description for the step of placing a sample of resorbable porous silicon into a living animal or human. Furthermore, as described above, original claims 29 and 31 do not provide written description for the claimed method. Therefore, the instant rejection is proper as amended and is maintained.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claim 46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 91-92 of copending Application No. 11/159,340 (copending '340) **is maintained** for the reasons of record restated below and because Applicants have not provided any substantive arguments traversing the instant rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and mutually obvious. Independent claim 46 of the instant application claims a method of growing natural host tissue in an implant comprising the step of placing a sample of resorbable porous silicon in a living animal or human and allowing the implanted resorbable porous silicon to degrade while in the living animal or human and be replaced with natural animal or human tissue. Independent claim 91 of copending '340 claims a method of treating an animal or human by (a) implanting into the human or animal a sample of porous silicon, and (b) allowing the tissue growth on the surface of the porous silicon, or allowing the porous silicon to corrode. The corrosion of porous silicon reads on resorbable silicon. The additional step, step (b), recited in claim 91 of copending '340 would obviously occur to the resorbable silicon implanted using the method of the instant

application after implantation, because resorbable silicon would be expected to corrode (i.e. dissolve). Therefore, the Examiner concludes that a person of ordinary skill in the art at the time of the instant invention would have found claims 46 and 49 *prima facie* obvious over claims 91-92 of copending '340.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

**Claims 46-48 are rejected. No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James H Alstrum-Acevedo/
Patent Examiner, Art Unit 1616
Technology Center 1600